Application No. 10/018,233
Filed: December 12, 2001
TC Art Unit: 1753
Confirmation No.: 8808

REMARKS

Claims 1-33 have been rejected by the Examiner under 35 U.S.C. §§ 112 and 103. Claims 1-33 are pending in the present application and claims 1, 2, 9 and 12 are amended herein. Support for the amendments can be found throughout the specification and claims as originally filed. No new matter has been added. Accordingly, claims 1-33 will be pending upon entry of the amendments herein.

Any amendments to the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicants reserve the rights to pursue the claims as originally filed in this or a separate application(s).

Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections in view of the above amendments and the remarks herein.

General Comments

The Examiner noted that the application is without an abstract of the disclosure as required by 37 C.F.R. § 1.72. Applicants have appropriately amended the specification to include an abstract. The included abstract replaces any abstract filed with the application and was also incorporated in corresponding International Application PCT/US00/17490 filed on June 23, 2000. Thus, Applicants have appropriately responded to the Examiner's statement and submit that the amended specification is in condition for allowance.

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Claim Objections

Claim 12 is objected to as the term "s^{-1}" should be changed to "(s^{-1})." The Examiner's suggestion is appreciated by Applicants and claim 12 has been amended appropriately. Thus, by way of amendment, Applicants submit that this objection has been overcome and reconsideration and withdrawal of the Examiner's objection are respectfully requested.

Claim Rejections 35 U.S.C. § 112, Second Paragraph

Claims 1-33 have been rejected for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention under 35 U.S.C. § 112, second paragraph.

Applicants respectfully respond to the foregoing rejections by way of amendments and remarks herein.

(A) The Examiner rejected claim 1 for being indefinite contending that the term "the target/sample mixture" lacks proper antecedent support. In response, Applicants have amended claim 1 to provide proper antecedent support for the term "the target/sample mixture." Thus, by way of amendment, Applicants submit that this rejection has been overcome.

(B) The Examiner rejected claim 2 for being indefinite suggesting that the term "the reference standard" lacks proper antecedent basis. Applicants, however, respectfully note that claim 1 provides proper antecedent basis for the term "the reference standard." Specifically, step (e) of claim 1 recites "a reference standard." Thus, in view of this clarification, Applicants respectfully submit that the rejection has been overcome.

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290

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(C) The Examiner rejected claim 7 for being indefinite asserting that the term "migration pattern" is unclear as both claims 1 and 2 refer to a migration pattern. In response, Applicants have amended claim 2 to recite a "reference migration pattern," which refers to the migration pattern of the reference standard. This amendment clarifies that the migration pattern recited in claim 1 is different from the reference standard migration pattern of claim 2. Thus, by way of amendment, Applicants submit that this rejection has been overcome.

(D) The Examiner rejected claim 9 noting that the term "thereof" should be changed to "the sewage." Although Applicants appreciate the Examiner's suggestion, the term "thereof" does not refer to "the sewage." The term, instead, refers to the complex materials recited in the Markush group of claim 9. Accordingly, to clarify the term, Applicants have amended the punctuation of claim 9. By way of amendment, Applicants submit that this rejection has been overcome.

Based on the foregoing amendments and remarks in Sections (A), (B), (C) and (D), Applicants respectfully request reconsideration and withdrawal of all of the Examiner's rejections under 35 U.S.C. § 112.

Claim Rejections 35 U.S.C. § 103

Claims 1-11 and 16-33 have been rejected under 35 U.S.C. § 103 as being unpatentable over EP 0 848251 A2 to Lui et al.

Applicants respectfully respond to the foregoing rejections by way of remarks herein.

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290

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The method claimed by Applicants is directed to screening a complex material for an unidentified candidate ligand that binds to a pre-selected target. In part, the claimed method includes providing separately (1) a mixture of a complex material and the pre-selected target and (2) a known competitive ligand. These analytes are injected into an electrophoretic capillary as a combination and are subjected to capillary electrophoresis.

The Examiner states that Lui et al. teach all of the limitations of the claimed method other than mixing the candidate ligand with the pre-selected target prior to being injected into the electrophoretic capillary. The Examiner also contends that it would have been obvious to one of ordinary skill in the art to mix the candidate ligand and pre-selected target before injection into the capillary. Applicants, however, respectfully disagree with the Examiner.

Lui et al. disclose a method for conducting online competitive binding assays via automated capillary electrophoretic systems. See column 7, lines 32 through 34. The method requires a first, second and third assay reagent, which are ***each*** separately introduced into the electrophoretic capillary. See column 7, lines 32 through 34. The Examiner suggests that (1) the first assay reagent is comparable to a competitive ligand, (2) the second assay reagent is comparable to a candidate ligand and (3) the third assay reagent is comparable to a pre-selected target. Thus, the Examiner asserts that it would be obvious to mix the second assay reagent with the third assay reagent before injection into the electrophoretic capillary.

Applicants respectfully contend that Lui et al. particularly teach away from mixing the second and third assay reagents prior

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GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290

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to injection such that it would not be obvious to mix these reagents prior to injection. More specifically, Lui et al. require separately subjecting ***each*** assay reagent to electrophoresis ***after*** injection. This requirement does not permit the second and third assay reagents to be mixed ***before*** capillary injection. The method disclosed in Figure 2 of Lui et al. for example teaches (1) injecting the first assay reagent and subjecting it to electrophoresis, (2) injecting the second assay reagent and subject it to electrophoresis and (3) injecting the third assay reagent and subject it to electrophoresis.

As a convenience to the Examiner and to contrast Lui et al. with the claimed method, Applicants have provided steps (a), (b) and (c) as amended in claim 1.

> (a) providing a mixture of the complex material and a predetermined concentration of the target, resulting in a target/sample mixture, and separately providing a predetermined concentration of a known, detectable, competitive ligand that binds to the target;
> (b) sequentially injecting into a capillary of a capillary electrophoresis instrument having a detector, a first plug of analyte and a second plug of analyte...
> (c) subjecting the first and second plugs to capillary electrophoresis...

These steps indicate that either the first or second plug of analyte is a mixture of the candidate ligand and the pre-selected target. Thus, claim 1 requires that these analytes be mixed before injection into the electrophoretic capillary. Lui et al. does not suggest to one of ordinary skill in the art to mix these analytes prior to injection as the reference teaches that the first, second and third assay reagents are to be subjected to capillary electrophoresis in succession. This teaching away from

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290

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claim 1 clearly does not provide the motivation required to render the claimed method obvious in view of Lui et al.

Lui et al. also clearly teach that different analyte complexes or mixtures are to be formed ***within*** a capillary column. See column 7, lines 47 through 48. For example, the reference discloses (1) a first and second assay reagent complex, (2) a second and third assay reagent complex and (3) a first and third assay reagent complex, ***each*** formed in a capillary column and detected through a detection means. See column 7, lines 46 through 48. Lui et al. continue requiring that the third assay reagent reacts with the previously and separately injected first and second assay reagents to form particular binding complexes or mixtures. See column 8, lines 1 though 18. Thus, Lui et al. do not allow any of the assay reagents to be mixed ***before*** injection into the electrophoretic capillary such that the claimed invention would be obvious.

Finally, Applicants respectfully guide the Examiner to one advantage of the invention disclosed by Lui et al. This advantage teaches that the art invention is useful for unattended automated clinical and diagnostic sample processing. See column 4, lines 9 through 11. Moreover, Lui et al. suggest that this advantage is facilitated when "the specific binding partner and ligand are ***each*** placed in individual vials and either may be used repeatedly to do multiple sample analysis." See column 4, lines 11 through 13. In view of this advantage, one of ordinary skill in the art would not be motivated to mix any of the reagents taught by Lui et al. ***prior*** to injection into an electrophoretic capillary. Contrary to the Examiner's suggestion, mixing the reagents disclosed in Lui et al. before capillary injection would avoid the described advantage of

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290

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the reference. This suggestion by the Examiner also contravenes settled law which does not permit a reference to be interpreted in a manner that would obviate the advantages that are therein disclosed and described.

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of all of the Examiner's rejections under 35 U.S.C. § 103.

CONCLUSION

Based on the entry of amendments and remarks presented herein, reconsideration and withdrawal of all the rejections and allowance of the application with all pending claims are respectfully requested.

The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

YURIY M. DUNAYEVSKIY ET AL.

By: Holliday C. Heine

Holliday C. Heine, Ph.D.
Registration No. 34,346
Attorney for Applicant(s)

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
Ten Post Office Square
Boston, MA 02109
Telephone: (617) 542-2290
Telecopier: (617) 451-0313

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WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290

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